ORAL ARGUMENT NOT YET SCHEDULED

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff-Appellant*, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, and ROBERT M. CALIFF, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION, *Defendant-Appellees*, MSN PHARMACEUTICALS INC. and MSN LABORATORIES PRIVATE LTD., *Intervenor-Appellees*.	No. 24-05235

NONBINDING STATEMENT OF ISSUES TO BE RAISED

1. Whether the Food and Drug Administration (FDA) violated the Administrative Procedure Act (APA) in denying Novartis Pharmaceuticals Corporation's citizen petitions and approving Intervenor-Appellees' Abbreviated

New Drug Application (ANDA) referencing Novartis's product ENTRESTO, where:

a. FDA rewrote the ENTRESTO labeling in a manner prohibited by the statute and FDA's own regulations when it approved a purported generic product referencing Novartis's product;

b. FDA left out critical safety instructions from the generic labeling it approved, contrary to the agency's binding regulations; and

c. The generic product does not have the same active ingredients as ENTRESTO, in violation of the statute and FDA's own regulations.

Respectfully submitted,

/s/ Catherine E. Stetson
CATHERINE E. STETSON
SUSAN M. COOK
MARLAN GOLDEN
HOGAN LOVELLS US LLP
555 Thirteenth Street, NW
Washington, DC 20004
Telephone: (202) 637-5491
Facsimile: (202) 637-5910
cate.stetson@hoganlovells.com

Dated: November 14, 2024

Attorneys for Novartis Pharmaceuticals Corporation

CERTIFICATE OF SERVICE

I certify that on November 14, 2024, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Catherine E. Stetson
Catherine E. Stetson